

What is claimed is:

1. A method of making polymeric spheres having an average diameter of between 0.01 and 10.0 microns, comprising the steps of:
  - a.) providing a polymer solution of a polymeric material dissolved in a first fluid, said first fluid consisting of a supercritical, critical or near-critical fluid; and,
  - b.) depressurizing said polymer solution as said polymer solution exits one or more orifices in the presence of a low solubility fluid, said low solubility fluid having low volatility and said polymeric material in a concentration which exceeds said solubility of said polymeric material in said low solubility fluid, said polymeric material forming spheres having an average diameter between 0.01 and 10.0 microns and said first fluid removed during depressurization.
2. The method of claim 1 wherein said spheres have an average diameter of between 0.1 to 1.0 microns.
3. The method of claim 1 wherein said polymer solution has a bioactive material, said bioactive material dissolved in said polymer solution or held in said polymer solution as a suspension or emulsion.
4. The method of claim 3 wherein said bioactive material is dissolved in said first fluid.
5. The method of claim 3 wherein said bioactive material is held as a suspension in said polymer solution.
6. The method of claim 3 wherein said bioactive material is held as an emulsion in said polymeric solution.
7. The method of claim 3 wherein said bioactive material is dissolved in a second fluid and said second is combined with said first fluid and polymeric material.
8. The method of claim 7 wherein said second fluid is a supercritical, critical or near-critical fluid.

9. The method of claim 7 wherein said bioactive material is held as a suspension in said second fluid.
10. The method of claim 3 wherein said bioactive material is held as an emulsion in said second fluid.
11. The method of claim 1 wherein said polymer solution is depressurized to ambient pressure.
12. The method of claim 1 wherein said low solubility fluid is selected from the group of solvents consisting of PVA, PBS, and liquid nitrogen.
13. The method of claim 1 wherein said polymer is selected from one or more of the group of polymers consisting of poly(L-lactic acid), poly(D, L-lactic acid), poly(glycolic acid) and carboxylic acid and ester derivatives thereof, poly(fumaric anhydride) and poly(sebacic anhydride) and derivatives thereof.
14. A method of making polymeric spheres having an average diameter of between 0.01 and 10.0 microns, comprising the steps of:
- a.) providing a polymer solution of a polymeric material in a first fluid, said first fluid consisting of a supercritical, critical or near-critical fluid;
  - b.) providing a second solution of a bioactive material in a second fluid;
  - c.) forming an admixture of said first solution and said second solution to form a third solution, said third solution comprising a supercritical, critical or near-critical fluid;
  - d.) depressurizing said third solution as said third solution exits one or more orifices in the presence of a low solubility fluid, said low solubility fluid having low volatility and said polymeric material in a concentration which exceeds said solubility of said polymeric material in said low solubility fluid, said polymeric material forming spheres having an average diameter of 0.01 to 10.0 microns, said spheres containing said bioactive material and said first fluid removed during depressurization.
15. The method of claim 14 wherein said spheres have an average diameter of between 0.1 to 1.0 microns.

16. An apparatus for forming one or more polymeric spheres having an average diameter of between 0.01 and 10.0 microns, comprising:

a.) an admixture vessel for receiving a polymer solution which polymer solution is a polymeric material dissolved in a first fluid, said first fluid consisting of a supercritical, critical or near-critical fluid;

b.) an orifice nozzle in communication with said admixture vessel for receiving said polymer solution; and,

c.) a depressurization vessel containing a low solubility fluid in communication with said orifice nozzle for receiving a stream of polymer solution as said polymer solution exits one or more orifices in the presence of said low solubility fluid, said low solubility fluid having low volatility and said polymeric material in a concentration which exceeds said solubility of said polymeric material in said low solubility fluid, said polymeric material forming spheres having an average diameter of 0.01 to 10.0 microns and said first fluid removed during depressurization.

17. The method of claim 16 wherein said spheres have an average diameter of between 0.1 to 1.0 microns.

18. The apparatus of claim 16 wherein said admixture vessel receives a bioactive material, said bioactive material dissolved in a solvent or held as a suspension in a fluid or held in an emulsion, and said bioactive material incorporated into said spheres during depressurization.

19. The apparatus of claim 16 wherein said apparatus further comprises a polymer vessel for forming a solution of a polymer in a supercritical, critical or near critical fluid, said polymer vessel in fluid communication with said admixture vessel.

20. The apparatus of claim 16 wherein said apparatus further comprises a bioactive material vessel for forming a suspension, solution or emulsion of said bioactive material in said polymer solution, said bioactive vessel in communication with said admixture vessel.